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Plaintiff, In Proper Person

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

Jin-Pyong Peter Yim,	<u> </u>	
Plaintiff)))	No
v.)))	COMPLAINT FOR DECLARATORY
National Institutes of Health,)	AND INJUNCTIVE RELIEF
Defendant))	

Jin-Pyong Peter Yim (Yim) as for its Complaint against above-captioned National Institutes of Health (NIH), alleges as follows:

Introduction

- 1. Defendant, NIH, recommends treatments for COVID-19 in its publication, "COVID-19 Treatment Guidelines" (the Guidelines). 1
- 2. Plaintiff, Yim, is a freelance journalist who has written articles for Trial Site News.²
- 3. The Guidelines' COVID-19 treatment recommendations are not binding. As stated in the publication: "Finally, it is important to stress that the rated treatment recommendations in these Guidelines should not be considered mandates. The choice of what to do or not to do for an individual patient is ultimately decided by the patient and their provider."
 - However, the Guidelines recommendations are widely cited in the media.^{3,4,5} 4.
- 5. In an update to the Guidelines on August 27, 202, NIH recommended against the use of Ivermectin in patients with COVID-19, except in a clinical trial.⁶
- 6. In an update to the Guidelines on January 14, 2021, NIH removed the recommendation against the use of Ivermectin in COVID-19. However, it stated: "There

¹ https://www.covid19treatmentguidelines.nih.gov/

² https://trialsitenews.com/

https://www.nytimes.com/interactive/2020/science/coronavirus-drugs-treatments.html

⁴ https://www.washingtonpost.com/outlook/2021/01/27/covid-19-experimental-treatments/

https://www.wsj.com/articles/youtube-cancels-the-u-s-senate-11612288061

are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of ivermectin for the treatment of COVID-19."⁷

- 7. Ivermectin is a generic drug that is approved for use in humans by the Food and Drug Administration.⁸
- 8. In the Guidelines, NIH states: "All recommendations included in the Guidelines are endorsed by a majority of Panel members". However, Yim has been unable to confirm that by emails to NIH.
- 9. Yim has also been unable to confirm that through a Freedom of Information Act (FOIA) (5 U.S.C. § 552 as amended) request to NIH. NIH has failed to respond to this request as required under FOIA.
- 10. For this request, NIH neither provided a determination letter as required under 5 U.S.C. § 512 nor produced any documents in response to the FOIA request. The FOIA request sought a document the NIH could easily have produced or could easily have responded by stating that no such document existed. Yim therefore brings this action seeking an order directing NIH to respond to the FOIA request.

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 $[\]underline{https://files.covid19 treatment guidelines.nih.gov/guidelines/archive/covid19 treatment guidelines-01-14-202}\\ \underline{1.pdf}$

PARTIES

- 11. Plaintiff, Yim is a United States citizen residing at 912 Primrose Ct, Belle Mead, NJ, 08502. He is a freelance journalist who has written articles for Trial Site News. 9,10,11,12 He is seeking information from NIH solely for the public interest. He has no financial interest in the use of Ivermectin.
- 12. Defendant, NIH is an agency within the executive branch of the United States government organized within the Department of Health and Human Services. NIH is an agency within 5 U.S.C § 552 (f).

JURISDICTION AND VENUE

13. This court has jurisdiction over this action pursuant to 5 U.S.C. § 552 (a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this district pursuant to 5 U.S.C. § 512 (a)(4)(B) and 28 U.S.C. § 1391.

FACTS

I. BACKGROUND

14. NIH states that there is "insufficient data" to this point, to recommend the use of Ivermectin in COVID-19.¹³ That view is shared by Merck who issued a statement on

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⁹ https://trialsitenews.com/the-ivermectin-recommendation-was-a-deception/

¹⁰ https://trialsitenews.com/nih-unable-to-comply-with-foia-on-its-ivermectin-recommendation/

¹¹ https://trialsitenews.com/systemic-unreported-protocol-violations-in-key-ivermectin-study/

¹² https://trialsitenews.com/jama-ivermectin-study-deceived-participants-on-study-drug/

February 4, 2021 about ivermectin: "No scientific basis for a potential therapeutic effect against COVID-19 from pre-clinical studies; No meaningful evidence for clinical activity or clinical efficacy in patients with COVID-19 disease, and; A concerning lack of safety data in the majority of studies." ¹⁴

- 15. Others disagree. The national governments of Slovakia¹⁵, Czech Republic¹⁶, Macedonia¹⁷, Belize¹⁸, Bolivia¹⁹ and Peru²⁰, the government of the province of Uttar Pradesh²¹ in India, and the government of Mexico City²² in Mexico, have all authorized the use of Ivermectin in COVID-19. The government of the state of Chiapas in Mexico conducted a mass distribution campaign of ivermectin.²³
- 16. Because of this controversy over the use of ivermectin in COVID-19, Yim seeks to better understand how NIH reached the Guidelines recommendation on ivermectin.

https://web.archive.org/web/20210324015218/https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/

https://trialsitenews.com/slovakia-becomes-the-first-eu-nation-to-formally-approve-ivermectin-for-both-prophylaxis-and-treatment-for-covid-19-patients/

https://www.extra.com.pe/actualidad/ivermectina-vuelve-a-ser-incluida-en-tratamiento-covid-19/?fbclid=lw AR2rZGL16z r gKSD EO1m4qFLjqubcHxw8wqb7yal8q4GOeTo0WQ1u0WWQ

https://indianexpress.com/article/india/up-new-protocol-ivermectin-to-replace-hcq-in-treatment-of-covid-patients-6545236/

https://aristeguinoticias.com/2901/mexico/secretaria-de-salud-de-cdmx-defiende-uso-de-ivermectina-para-casos-positivos-de-covid-19/

https://www.sie7edechiapas.com/post/repartir%C3%A1n-10-mil-kits-con-ivermectina-para-combatir-covid-19-en-tuxtla

¹¹

¹⁶ https://www.youtube.com/watch?v=e40EYxdlflk

¹⁷ https://www.archyde.com/ivermectin-arrives-in-macedonia-as-a-treatment-for-covid/

¹⁸ https://trialsitenews.com/central-american-nation-of-belize-authorizes-use-of-ivermectin-for-covid-19/

¹⁹ https://www.nature.com/articles/d41586-020-02958-2

²⁰

- 17. Updates to the Guidelines can be approved in one of two ways. The first is through a vote of the COVID-19 Treatment Guidelines Panel (Panel). The second is by the Panel co-chairs without a vote of the Panel. ²⁴
- 18. It is unclear when a vote is required to update a Guidelines recommendation. The Guidelines state: "All recommendations included in the Guidelines are endorsed by a majority of Panel members." However, the Guidelines also state: "Updates to existing sections that do not affect the rated recommendations are approved by Panel co-chairs without a Panel vote."
- 19. The current Guidelines recommendation for Ivermectin is not a "rated recommendation". Therefore, the current Guidelines recommendation on Ivermectin could have been approved by the Panel co-chairs without a Panel vote.
- 20. Two members of the Panel were asked by Yim in an email on January 27, 2021: "Can you tell me if you participated in a vote to update the latest recommendation on ivermectin in the NIH COVID-19 Treatment Guidelines? The Panel members did not respond directly. Instead, my question was forwarded to the Section Chief for Controlled Correspondence and Public Inquiries. She responded on January 29, 2021: "Information on the Method of Synthesizing Data and Formulating Recommendations may be found on pages 18-20 of the *Coronavirus Disease 2019 (COVID-19) Treatment Guidelines* …" (Exhibit A)

²⁴ https://www.covid19treatmentguidelines.nih.gov/introduction/

II. THE FOIA REQUEST

- 21. Plaintiff, Yim, submitted the following valid FOIA request to NIH: "All updates to the Coronavirus Disease 2019 (COVID-19) Treatment Guidelines that were endorsed by a vote of the Panel. (Date Range for Record Search: From 01/01/2021 To 01/28/2021)" The request was assigned an identifier by NIH of Case # 55822. The request was received on January 29, 2021.
- 22. There was only one update to the Guidelines during the time period in the FOIA request and that update was for the Guidelines' recommendation on ivermectin. Therefore, the net effect of the FOIA request is to determine if a vote was held on the Guidelines Ivermectin recommendation.
- 23. The FOIA request was accompanied by an expedite request. The justification for the expedite request was: "The information requested in necessary for the public to have confidence in how the NIH is handling the pandemic."
- 24. On February 11, 2021, NIH responded to the expedite request. NIH denied the expedite request. In denying the expedite request, the NIH stated: "Unfortunately, your request does not meet the standard of 'compelling need'. Therefore, I am denying your request for expedited processing." (Exhibit B)

III. NIH FAILS TO PROPERLY RESPOND OR PRODUCE ANY DOCUMENTS

25. Observing that the NIH had not responded to the FOIA request within the time of 20 business days as required by statute, on March 7, 2021, Yim requested an estimated

completion date for the FOIA request from NIH. (Exhibit C) NIH responded: "Your request is being processed and is in the queue behind all other requests received ahead of yours, following HHS FOIA 'first-in, first-out' guidelines. Once review begins on any records responsive to your request, the NIH will provide an estimated completion date." (Exhibit D)

- 26. NIH is required to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reason therefore." 5 U.S.C. § 552 (a)(6)(A)(i). At a minimum, within 20 days of receiving each of Yim's requests, NIH was required by 5 U.S. C. § 552(a)(6)(A)(i) to (i) gather and review the requested records or seek statutorily permitted extension; (i)) determine and communicate to Yim the scope of any responsive records it intended to produce or withhold and the reasons for any withholdings; and (iii) inform Yim that it had the right to appeal NIH's determination. *See e.g. Citizens for Responsibility and Ethics in Washington v. Federal Election Commission*, 711 F.3d 180, 188-89 (D.C. Cir. 2013).
- 27. Instead, despite the passage of more than 20 business days since NIH received the above request, it has failed to provide the statutorily required response including failing to seek a permitted extension; determine and communicate to Yim the scope of any responsive records it intended to produce or withhold and the reasons for withholding; or inform Yim of right to appeal.
- 28. For these reasons, NIH has failed to abide by the requirements of FOIA and has forced Yim to come before this Court to seek an order directing NIH to expeditiously produce all documents responsive to its FOIA request or to state that no documents exist.

 The production of the documents or the disclosure that the documents do not exist does not

require extensive research. Therefore, the response time should have been short. The information is simply too important to the current public discourse regarding the COVID-19 pandemic to allow NIH to withhold such information from public scrutiny.

REQUESTED RELIEF

- 29. WHEREFORE, Plaintiff prays that the Court:
 - a. Provide for expeditious proceedings in this action.
 - b. Enter an Order directing NIH, within 10 days to produce the requested documents or to state that such documents do not exist.
 - c. Grant such other and further relief as the Court may deem just and proper.

March 26, 2021

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